REMARKS

Independent claims 1, 7 and 9 have been amended to clarify that Applicants' invention pertains to oral liquid pharmaceutical compositions. Claims 1, 3 through 9, and 11 through 17 are pending in this application. No new matter has been added by way of the amendments herein above, and no new issues have been raised by the same.

Rejections under 35 U.S.C. §103:

The Examiner rejected claims 1, 3, 6, 9, 11, 14 and 17 under 35 U.S.C. §103(a) as being unpatentable over Yu et al. U.S. Patent No. 5,071,643 in combination with Honour et al. U.S. Patent No. 5,529,923 in combination with Veech U.S. Patent No. 6,020,007.

The Examiner also rejected claims 4, 5, 7, 8, 12, 13, 15 and 16 under 35 U.S.C. §103(a) as being unpatentable over Yu et al. U.S. Patent No. 5,071,643 in combination with Honour et al. U.S. Patent No. 5,529,923 in combination with Veech U.S. Patent No. 6,020,007 in combination with Shelley et al. U.S. Patent No. 5,505,961.

Applicants respectfully traverse these rejections for the following reasons.

The Yu Reference

The Examiner argues that the Yu reference teaches an acetaminophen-containing composition for softgel encapsulation. The reference does not teach the use of a lactate salt in the composition.

The Honour Reference

The Examiner argues that the Honour reference teaches a composition containing sodium lactate. The reference teaches the use of a sodium lactate in a composition for *intravenous* administration of a bacterium. The reference does not teach acetaminophen or an oral dosage form containing a lactate salt.

The Veech Reference

The Examiner argues that l-forms of salts are preferred for therapeutic electrolyte solutions. The reference does not teach acetaminophen, encapsulated dosage forms and l-lactate as a solvent system ingredient.

The Shelley Reference (second rejection only)

In the second rejection under 35 U.S.C. 103, the Examiner further applies the Shelley reference. The Examiner argues that Shelley teaches a composition containing acetaminophen and potassium acetate. Applicants are aware of this – the instant invention is an improvement of the Shelley system as discussed in the "Background of the Invention" section of Applicants' specification on page 3.

The Combination of References

The teachings of the Examiner's applied references as compared to Applicants' invention can be summarized as follows:

Yu	acetaminophen + capsule dosage form + oral liquid composition
Honour	sodium lactate (*intravenous administration of bacterium*)
Veech	l-form salt (*electrolyte solution*)
Shelley	acetaminophen + capsule dosage form + oral liquid composition + potassium acetate

A sensible, technologically sound pathway that would have lead one of ordinary skill to Applicants' invention is not seen from the Examiner's explanation. The proper contexts of the cited teachings, together with the absence of pertinent teachings, instead would have lead one of ordinary skill in the art to a series of technology "cliffs" short of reaching the invention. One of the important aspects of the invention is the use of the l-lactate salt in the acetaminophen-containing composition. Indeed, the combination of teachings relevant to an oral liquid composition is absent the fair teaching or suggestion of l-lactate salt together with acetaminophen. This is the very minimum of that which the

Examiner's "hindsight" must fabricate. Clearly, the hindsight applied by the Examiner does not fall within the acceptable amount discussed in *In re McLaughlin* (cited by the Examiner).

To the extent that the Examiner attempts to rely upon "liquid" to combine the references, Applicants have amended the pending claims to clarify the context and nature of Applicants' invention, i.e., that the invention relates to an *oral liquid* pharmaceutical composition. This amendment carries with it both the physical form and the particular administration route of the composition.

The Examiner's Response to Applicants' Previous Argument

In response to Applicants' arguments pertaining to the technological context of the references cited by the Examiner, the Examiner maintained his motivation to combine the references based on the view that "They are all liquid formulations." and "Therefore, it is the position of the Examiner that these references are related and NOT technologically non-sensical."

Accordingly, the Examiner motivation to combine the references has its foundation on the erroneous perception that any and all liquid formulations and their respective ingredients and administration routes (and their associated physiological conditions) are readily interchangeable with one another to one of ordinary skill. It is Applicants' position again that these references and their contexts, as explained in detail above, render their combination technologically non-sensical. This is because shared teachings of a composition's physical state being a liquid cannot provide a scientifically sound basis to pick and choose ingredients from references for one of ordinary skill in the art. In addition to this being a well-understood principle in the chemical field, Applicants' have elaborated in the specification as to difficulties balancing the various properties associated with various ingredients and their combinations in encapsulated pharmaceutical fill compositions. Furthermore, the unpredictability and unexpected

outcome of various ingredients is presented in Applicant's experimental data in the specification, which the Examiner has apparently chosen to ignore – again. Indeed, Applicants have demonstrated the sensitivity of ingredients and have surprisingly discovered a high degree of acetaminophen concentration solubility.

In summary, the Examiner has not provided a collection of teachings, alone or in combination, that would render Applicants' invention to be obvious to a person having ordinary skill in the art.

Given the above, Applicants' claimed invention is not unpatentable over the cited references within the proper meaning of 35 U.S.C. §103. These rejections should, therefore, be withdrawn.

Conclusion:

In light of the above amendments and the accompanying remarks, it is believed that the application is now in condition for allowance, and prompt notification to that effect is earnestly solicited. The Examiner is invited to contact the undersigned to discuss the application on the merits if it is believed that such discussion would expedite the prosecution.

Respectfully submitted,

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